SUMMARY OF AND RESPONSE TO COMMENTS RECEIVED DURING THE PUBLIC COMMENT PERIOD
FOR
GUIDELINES FOR ASSESSING ECOLOGICAL RISKS POSED BY CHEMICALS-DEVELOPMENTAL PLAN

MAY 1998

This document provides a summary of the comments received during the 60-day public comment period (November 21, 1997 - January 20, 1998) and also summarizes OEHHA's response to the comments on the *Guidelines for Assessing Ecological Risks Posed by Chemicals-Developmental Plan*. In large part, public comments received could be categorized under several broad issues related to ecological risk assessment. OEHHA's responses attempt to address these broader issues and are based upon interpretation of the comments by OEHHA staff.

Issue 1. When is an ecological risk assessment needed? a) Define in which situations an ecological risk assessment (ERA) is required. b) Will the guidelines be adopted as regulations? c) In what situations shall Cal/EPA guidance be used and when shall Cal/EPA program specific guidance be used?

Reply: a) The mandate for, and scope of, the guidelines is to provide general guidance on <u>how</u> to conduct ERAs rather than provide specific criteria for <u>when</u> an ERA is needed. Depending on the particular situation, specific legal requirements will determine when to do an ERA. b) There is currently no intent or mandate to adopt Cal/EPA guidance as regulation. c) Cal/EPA guidance will be available to Cal/EPA Boards and Departments to use. The guidance will be applicable in all situations where program specific guidance is complemented or no program specific or legally binding guidance exists. It is at the Boards' and Departments' discretion to adopt these guidelines to meet their program specific needs. Clarifying language has been added to the Developmental Plan under "Scope and Intent".

Issue 2. Non-chemical stressors. The *Developmental Plan* is not balanced in its treatment of the three main types of ecological stressors (i.e., biological, physical, chemical). This is a critical deficiency since the role of non-chemical stressors as the source or cause of risk to ecological resources can be significant.

Reply: We agree with commentors that guidance on consideration of non-chemical stressors is needed in ecological risk assessment. As described in the current Developmental Plan, our guidelines will include, in addition to other resources, a technical document which will address non-chemical stressors (see section on Non-Chemical Stressors). However, our current and projected resources do not permit us to develop <u>extensive</u> guidance in this area, nor do we envision providing guidance on assessment of non-chemical stressors in the absence of chemical stressors. Our reasons for <u>restricting</u> guidance in these areas include: 1) Cal/EPA's mandates for ecological protection are primarily chemically driven; 2) if appropriate, we will adopt US EPA's guidance in the area of non-chemical stressors; 3) we currently have insufficient resources to develop extensive guidance on the evaluation of non-chemical stressors.

Issue 3. Peer review. a) *Ad hoc* peer review will not provide openness, balance, and possible rigor in guideline development. A more formalized process with clear criteria for selection of peer reviewers should be considered. b) Will the peer review process be formalized according to 57004 Health & Safety Code (SB 1320)?

Reply: a) We disagree that ad hoc peer review will not provide openness, balance, and rigor in the guidelines development process. Due to the broad range of topics that the guidelines will encompass, it is anticipated that experts from various fields will be needed for reviews. This will require a reviewer group with flexible and frequently changing membership, rather than a static review panel. To ensure balanced representation, technical reviewers from government, academia, non-profit/environmental groups and the private sector will be invited. The use of ad hoc peer reviewers who are experts from outside of California state government will provide independent recommendations on technical and scientific aspects of the guidelines, and may also provide review in areas of expertise not widely available within Cal/EPA. Since the guidelines are planned to be released in a phased manner, this will provide ample opportunity to seek feedback on guidelines progress from interested parties on an on-going, or periodic, basis. b) This peer review process will conform to all applicable requirements of Senate Bill 1320 (SB 1320, Statutes of 1997, Chapter 295). Clarifications regarding these two comments have been made in the section entitled "Guidelines Review and Interested Party Input" of the Developmental Plan.

Issue 4. Stakeholder input. a) Provide opportunities for regular guidelines review; b) hold workshops to discuss technical issues; c) involve all stakeholders in that process.

Reply: a), b), c) *To ensure that the guidelines meet the needs of the Cal/EPA ERA community, OEHHA will continue to seek input from interested parties. Depending upon factors such as available resources and level of interest, this may include further workshops on ERA guidance topics and issues. Opportunity for input will also be provided through several levels of review. The review process will help ensure that the proposed guidelines incorporate the best available science and are useful to the Boards and Departments and the regulated community. Clarifying language has been added under the section "Guidelines Review and Interested Party Input" of the Developmental Plan.*

Issue 5. Risk management decisions. a) Ecological risk management actions themselves have ecological impacts. Assessment of management options using environmental valuation methods, such as Net Environmental Benefit Analysis (NEBA) or Habitat Equivalency Analysis (HEA) should be encouraged when management actions are proposed. Cal/EPA should develop guidance on use of NEBA and similar approaches. b) Consider the need to assess "ecological value" by looking at current and future land use scenarios; consider impact of proposed remedial activities on the ecological value of the site and/or habitat; consider off-site habitat restoration.

Reply: a) Both HEA and NEBA are methodologies designed to address risk management issues (i.e., restoration options in Natural Resource Damage Assessments). Since both HEA and NEBA apply to risk management decisions (i.e., restoration and compensation), it is outside of our

mandate to address these issues as part of our guidelines. b) Considering the need to assess "ecological value" is also clearly a risk management issue and is therefore not a part of these guidelines. The question of risk management decisions has been clarified in "Scope and Intent" in the Developmental Plan.

Issue 6. Risk characterization. The weight-of-evidence approach should be used in characterizing ecological risk. The current document has not addressed this concept. This is a shortcoming that should be corrected.

Reply: We agree that weight-of-evidence approach should be addressed in risk characterization. Based upon review of US EPA's guidance on risk characterization, we will decide whether or not it is necessary to develop our own guidance in this area. Generally, we expect guidance in this area to be applicable to a wide variety of situations, thus requiring less interpretation for California-specific needs.

Issue 7. California specificity. Consider carefully when geographical differences really influence an ERA. ERA has many common elements that are not heavily influenced by geography, stressor type, or receptor type. There is concern that heavy emphasis on California specific data (i.e., data development) may incur substantial cost and time and lead to burdensome data generation.

Reply: The emphasis on California specific data and unique wildlife, geography, etc. is <u>not</u> intended to require development of new data, use of California specific tests, or prohibit the use of surrogate data. Rather, California specific data (where available and applicable) should be used to improve the science and quality of ecological risk assessments. OEHHA intends to provide sources of existing California specific data for risk assessors such as the California Wildlife Exposure Factor and Toxicity Database (Cal/Ecotox), the Ecological Endpoint Selection Guidance and others described as technical resources in the Developmental Plan. No specific changes to this topic have been made in the Developmental Plan.

Issue 8. Role of risk manager. Cal/EPA should discuss clearly the role of the risk manager(s) in the ERA and decision making process, and define risk manager broadly to include individuals from the public and private sectors. Emphasis needs to be placed on the planning and dialogue between the risk assessor and risk manager at the start of the process.

Reply. We agree that risk manager-risk assessor interaction is a critical issue in ERA. Risk management input into the ERA process must address both scientific and policy concerns. We anticipate harmonizing with US EPA's guidelines, which provide general guidance on risk management input into the ERA process. More specific guidance on the role of the risk manager in ERA will be the responsibility of the specific programs within Cal/EPA. No changes were made to the Developmental Plan in response to these comments.

Issue 9. Risk manager-risk assessor communication. The draft *Developmental Plan* suggests the focus of the Risk Communication technical document will be communication from the risk

assessor to the risk manager. Commentors strongly encourage Cal/EPA to expand this document to also include guiding principles for risk managers to provide effective and clear descriptions of management goals to risk assessors.

Reply: We agree that two way communication between risk management and risk assessment is essential for the ERA process. It was not our intent to convey that communication between risk assessor and risk manager should be a one-way process. Rather, this technical resource document is intended to provide guiding principles and reference material to the risk assessor when communicating the findings of a risk assessment to the risk manager. (i.e., clarity of language and terms used; underlying principles and assumptions made during the risk assessment process; context and relevance of assumptions made, extrapolations, uncertainties etc). This is described in the section on "Communication of Risk Assessment Findings" in the Developmental Plan.

Issue 10. Cal/Ecotox Database. What sort of quality control criteria must a study meet in order to be accepted into the database? How will the database be used?

Reply: Cal/Ecotox was designed to augment the US EPA Wildlife Exposure Factor Handbook (USEPA, 1993) by emphasizing California-specific needs for western species and ecosystems coverage. Cal/Ecotox is intended to furnish the risk assessment community with a convenient source of basic scientific information on California wildlife species and contaminant effects. The database contains original data retrieved from the primary literature. Any database user must apply his/her own data quality objectives to determine which data will be useful in an ecological risk assessment. This approach was selected because data quality objectives may vary considerably among users. Clarifying language has been added to the Developmental Plan (see section on California Exposure Factor and Toxicity Database). Guidance on the use of this database for risk assessment purposes will be provided with the database.

Comment 11. Harmonization. Harmonize guidelines with US EPA

Reply: It is our intent (and stated so in the Developmental Plan) to harmonize as much as possible with US EPA's guidelines.

Comment 12. Endpoint selection. Develop endpoint selection sooner; include specific habitats (e.g., effluent dependent waters).

Reply: We expect to adhere to the timeline for technical resources development outlined in the Developmental Plan unless resources change and do not permit us to do so. Ecological endpoint selection is planned to begin in early 1999. We will not address specific habitats at the level of detail suggested by the commentor but will address general habitat types.

Comment 13. Web-access. In addition to ring binder format, guidance should be made available on web.

Reply: Guidance will be made available through the Internet. Our current Internet address is ***www.calepa.cahwnet.gov/oehha.***

Comment 14. Population model. Cal/EPA should conduct reality checks routinely through the development and validation of this model.

Reply: We agree that verification studies are essential for model development and use; such studies will be conducted prior to release of the model. This intent is stated in the Developmental Plan in the "Population Model for Ecological Risk Assessment" section.

References

SB 1320. Statutes of 1997, Chapter 295.

US EPA. 1993a. Wildlife Exposure Factors Handbook. Volume I. EPA/600/R-93/187a. Washington, DC.

US EPA. 1993b. Wildlife Exposure Factors Handbook. Volume II. Appendix: Literature Review Database. EPA/600/R-93/187b. Washington, DC.

US EPA. 1996. Proposed Guidelines for Ecological Risk Assessment. Office of Research and Development. EPA/630/R-95/002B. Washington, DC.